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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,598

09/10/2003

Miri Seiberg

JBP-430-CIP1

5368

27777 7590 12/15/2008
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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

12/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/659,598	Applicant(s) SEIBERG ET AL.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The response filed on **9/12/08** has been entered.
2. Applicant's argument filed on 9/12/08 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 73-86 are pending in this office action.
5. The rejection of claims 79-86 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claims.
6. Claims 73-78 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Meybeck et al., US 5,034,228 in view of Sessa et al. (1992) and Seiberg et al. J. (1997) for the reasons made of record in Paper No. 20080512 and as follows.

The affidavit under 37 CFR 1.132 filed on 9/12/08 is insufficient to overcome the rejection of claims 73-86 based upon the 103(a) rejection as set forth in the last Office action because: All that is required of the claims is to have a non-denatured soy extract (see claim 73 for example). In contrast, denatured, as understood by one of ordinary skill in the art, is a structural change in a molecule. Meybeck teaches a product of soy

Art Unit: 1618

extract-soya lecithin, tretinoin and a solvent which is not an alcohol. Therefore denaturation of the lecithin would not occur.

In arguendo, even if the solvent is found to denature the extract, the “active agent –trypsin” will still be present in the soya lecithin whether denatured or non-denatured. Therefore it would be expected that trypsin (the active agent) would react with tretinoin to give the same result of treating acne, as claimed (see claim 73 for example).

Applicant argues: that the Meybeck et al teaching relates to hydrous lipidic lamellar phases or liposomes containing as an active agent, a retinoid or a structural analogue of retinoid and that the said composition is more efficient against acne. Applicant further argues that lecithin is removed from soybeans using organic solvents and that organic solvent tend to denature proteins and that Meybeck fail to teach that the soya lecithin should be processed so as to maintain soy trypsin inhibitory activity and that the teaching of Meybeck et al would not lead one of ordinary skill in the art to invent the instant claimed application. Specifically, Applicant argues that Meybeck et al do not teach a soy extract containing soybean from soya lecithin.

Applicant further argues that Sessa et al relates to the determination that trypsin inhibitor is present in toasted soybean flour, and that Sessa et al does not remedy the deficit of Meybeck et al. Applicant also states that Sessa merely indicates that there is trypsin inhibitor in soybean flour.

Lastly, Applicant argues that Seiberg et al teaches the use of trypsin in inducing desquarmination and utriculi-epidermal differentiation in skin, and that Seiberg et al teaches away from the claim invention.

In Response: With regard to the Meybeck et al., col. 3 bridging col. 4 (see Example 1) discloses a suspension of soya lecithin, 0.1 g tretinoin (see col. 3, lines 60-65). Accordingly, the limitation set forth in claim 73 is therefore met. As to the limitation of non-denatured soybean extract, soya lecithin is considered as a *non denatured* extract of soybean (giving its broadest claim interpretation- the extract product should be non-denatured regardless of how it is obtained). Meybeck do not teach that the soy lecithin is defatted, which is considered a denatured soylecithin. All the claims require is a non-denatured soybean extract having a trypsin inhibiting activity. Meybeck, as indicated by Applicant, states clearly the formulation is employed for the treatment of acne, the claims recite a method of treating acne, and therefore the limitations as set forth in the claims are met by the teaching of Meybeck.

The introduction of Sessa shows that, and also admitted by applicant, that there is trypsin in soybean flour. Seiberg was introduced for its teaching that acne is eliminated by trypsin treatment. Therefore, the combined knowledge of the cited prior art would have led one of ordinary skill in the art to formulate a formulation comprising a tretinoin from a non-denatured soybean extract that is employed for the treatment of acne.

Careful thought has been given to the arguments, but are found unpersuasive and the rejection is maintained as in the last office action of record.

7. Claims 79-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meybeck et al., US 5,034,228 in view of Sessa et al. (1992) and Seiberg et al. (1997) for

Art Unit: 1618

the reasons made of record in Paper No. 20080512 as applied claims 73-78 and as follows.

Applicant argues: that the references (i.e., Meybeck, Sessa and Seiberg do not suggest the claim invention taken individually or separately.

In response: As set forth above in ¶ 6, the references and teachings are applied here as above.

Meybeck teaches 2 g of soy lecithin and 0.1 g of tretinoin which examiner has interpreted to be within the claim invention of 79, 81-83 and 85-86. See col. 3, line 62. One of ordinary skill in the art would be motivated to optimize the concentration of the active agents for the treatment of acne because it is known in the art that topical application of the retinoids in the past gave undesirable effects such as irritation. See col. 1, lines 48-56 (Meybeck et al). Based on that the determination of a dosage having the optimum therapeutic index is well within the level of the ordinary skill in the art, and the artisan would be motivated to determine the optimum amounts to get the maximum effect of the drug, hence the reference makes obvious the instant invention.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1618

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S.V.G./

/Robert C. Hayes/

Application/Control Number: 10/659,598

Page 7

Art Unit: 1618

Examiner, Art Unit 1618
12/02/08

Primary Examiner, Art Unit 1649